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LIMITATIONS AND EXCEPTIONS IN THE WIPO INSTRUMENT ON GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

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ABSTRACT

One of the hot topics in the World Intellectual Property Organization (WIPO) diplomatic conference on an instrument on “Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources” is whether and what exceptions language should be included in the text. At the brief public report from Committee I on May 15, 2024, the Chair reported: “There appears to be adequate support for eliminating Article 4, limitations and exceptions. Some parties opposed.” This Blog provides some background information on the Article and analysis of potentially applicable models and concepts for the provision, including analysis of similar treaties with no exceptions.

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TEXT OF THE DRAFT TREATY

The basic requirement of the proposed instrument would be to oblige members to require patent holders to disclose uses of genetic resources and associated traditional knowledge.² The goals include to prevent patents from being granted erroneously for inventions that are not novel or inventive, and to prevent the misappropriation that does not comply with access and benefit sharing regulations, such as those adopted to comply with Article 15 of the Convention on Biological Diversity.

The draft text of the treaty that is being used as the basis of the negotiation includes a “limitations and exceptions” provision in Article 4, which reads:

ARTICLE 4, EXCEPTIONS AND LIMITATIONS

In complying with the obligation set forth in Article 3, Contracting Parties may, in special cases, adopt justifiable exceptions and limitations necessary to protect the public interest, provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this Instrument or mutual supportiveness with other Instruments.

Article 3 of the treaty provides the main requirement of the instrument, which is to “require [patent] applicants to disclose” the country of origin or

² See https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=625814

source of genetic resources and the use of traditional knowledge associated with genetic resources.

Article 3.3 of the IGC Treaty provides a built-in exception where “none of the information ... is known to the applicant.” Thus, the purpose of Article 4 appears to be to allow cases of non-disclosure where that information is known by the applicant.

The text and structure of Article 4 is loosely based on the so-called “three-step test” for limitations and exceptions to exclusive rights in intellectual property treaties. The three-step test was introduced as part of the Stockholm Act of the Berne Convention in 1967, which introduced an obligation to grant copyright holders an exclusive right of reproduction. Article 9(2) included a general authorization for countries to adopt exceptions for any purpose, subject to a three-factor test protecting the interests of exclusive right holders:

It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.

The history of the three-step test from 1971 to the present day has seen its evolution from a relatively permissive principle, framed as a right of countries (“it shall be a matter for legislation”), to one that has increasingly been framed and interpreted to confine the scope of permissible limitations and exceptions to copyright protection.³ A major critique of the 3-step test in copyright is that it does not explicitly mention the interests of the public (or of “third parties”) that must be balanced against the private interests of right holders.⁴

³ See TRIPS (1994) (“shall confine”); WTO 110(5) Case (interpreting the three steps to be cumulative rather than a holistic analysis).

⁴ See Max Planck, DECLARATION A BALANCED INTERPRETATION OF THE “THREE-STEP TEST” IN COPYRIGHT LAW, https://www.ip.mpg.de/fileadmin/ipmpg/content/forschung_aktuell/01_balanced/declaration_three_step_test_final_english1.pdf at 2 (“In determining the scope of application of limitations and exceptions, the Three-Step Test should not take into account only the interests of right holders. The need to give equal consideration to third party interests is confirmed explicitly in the Three-Step Test as applied in industrial property law (Art. 17, Art. 26(2) and Art. 30 TRIPS).”). In practice, “[t]he fact that third party interests are not explicitly mentioned in the Three-Step Test as applied in copyright law does not detract from the necessity of taking such interests into account.” The three step test involves “the

The three step-test in the IGC Treaty is quite broad and flexible, which responds to some of the criticism of previous versions in intellectual property treaties. The Article usefully used the enabling (“may ... adopt”) instead of confining (“shall confine”) framing. In the first “step” of the test, it eliminates the word “certain” from the special cases clause, which may be useful in establishing that open general exceptions may be permissible. The second two elements, or steps, set up a balance between two public values -- the “the public interest” in a country and “the implementation of this Instrument or mutual supportiveness with other Instruments.”

RELATION TO OTHER INSTRUMENTS

For most countries, this new requirement would be in addition to the information required to be disclosed by Article 29 of the WTO TRIPS Agreement, which states:

Article 29. Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.

The IGC Treaty must also be read against the background of the access and benefit sharing requirements of the Convention on Biological Diversity (CBD). In the light of these CBD provisions, the disclosure requirement in Article 3 Basic Proposal acquires financial connotations: the disclosure offers information that may be used to require compensation or informed consent negotiations under Article 15(5) of the CBD.

JUSTIFICATIONS FOR EXCEPTIONS

The primary justification for an exception to the IGC Treaty’s disclosure requirement may be to speed research using genetic materials. An

necessary balancing of interests between different classes of rights holders or between rightholders and the larger general public.” *Id.*

abbreviated literature review suggests some support for this point in at least some countries.⁵ For countries that desire to implement the treaty with a more robust regulatory structure, it is conceivable that a lack of resources or time for regulatory change may prevent immediate compliance.

Fears of the effects of *public* disclosure of the required information could be addressed without an exception. The IGC treaty, like TRIPS Article 29, requires disclosure only to the government processing the application, not necessarily to the public. In the U.S.A. and Japan, for example, it is possible to grant so-called “secret patents” for security related technology where the inventing firm receives exclusivity, but the invention is only released to other firms with special clearances.⁶ Similarly, it may be possible to waive public disclosure of genetic resource or traditional knowledge information, for example to protect the identity or location of a community or to prevent the further disclosure of closely held or sacred traditional knowledge.

JUSTIFICATIONS FOR A RESTRICTED EXCEPTION

On the other side of the policy balance are the rights and interests of indigenous and local communities.

Under the traditional copyright three step test, the primary interest examined is that of the right holder against the interests of the public. Under the IGC treaty, the government is the custodian of the rights over genetic resources and the representative of the public interest. Since the state is

⁵ Much of the academic literature in this area relies on information from or has been funded by industry stakeholders. See, e.g. Amirkia V., Heinrich M. (2015). *Natural products and drug discovery: A survey of stakeholders in industry and academia*. Front. Pharmacol. (Section Exp. Pharmacol. Drug Discov.) 6, 237. 10.3389/fphar.2015.00237; Heinrich M, Scotti F, Andrade-Cetto A, et. al, *Access and Benefit Sharing Under the Nagoya Protocol- Quo Vadis? Six Latin American Case Studies Assessing Opportunities and Risk*. Front Pharmacol. 2020 Jun 8;11:765. doi: 10.3389/fphar.2020.00765. PMID: 32581783 (reporting that the implementation of access and benefit sharing requirements varied widely in six countries studies and that requirements to engage in a consultation processes with stakeholders delayed or dissuaded some research); Ebert AW, et al. *Critical Review of the Increasing Complexity of Access and Benefit-Sharing Policies of Genetic Resources for Genebank Curators and Plant Breeders-A Public and Private Sector Perspective*. Plants (Basel). 2023 Aug 19;12(16):2992. doi: 10.3390/plants12162992; *Economic Impact of Disclosure Requirements In Patent Applications For Genetic Resources'-Based Innovation, Commissioned by Ifpma and Crop Life International* https://backslashcoding.com/work/old_ifpma/wp-content/uploads/2018/06/Economic-impact-DRs-for-GRs-final-report_June2018.pdf (industry funded study claiming significant delay in development of patents because of access and benefit sharing requirements).

⁶ In the USA, the Invention Secret Act allows the United States government to classify patents under "Secrecy Orders", which indefinitely restrict public knowledge of them.

itself making the decision, one can assume its interest in safeguarding genetic resources may be represented in any decision to waive a disclosure requirement. Accordingly, a broad and flexible exception may be in the interest of government members of the treaty and the public at large.⁷

The main party that may desire more restricted exceptions may be Indigenous Peoples and local communities, who may be underrepresented in government decisions. As Peter Yu writes:

Indigenous Peoples may fear that a more relaxed three-step test will invite abuse in those contracting states that are reluctant to strengthen the protection of genetic resources and associated TK. For instance, these states could introduce broad limitations and exceptions to undermine the hard-fought obligations in the finalized instrument, including provisions that “run counter [to] indigenous peoples’ right to self determination and the principle of [free, prior, and informed consent].” To close these loopholes, Indigenous Peoples therefore prefer a more restrictive three-step test—at times even tighter than the one found in the TRIPS Agreement and other international trade and intellectual property agreements.⁸

OTHER SIMILAR TREATIES LACKING EXCEPTIONS

Similar requirements with respect to disclosure obligations in international agreements do not contain explicit exceptions, perhaps because of the built in flexibilities in the requirements.

There are no exceptions to the disclosure requirements in TRIPS Article 29, which requires patent applicants “to disclose the invention in a manner sufficiently clear and complete” for the invention to be used by others. There do not appear to be any justifications for waiving this requirement since disclosing the invention is the very purpose of a patent. As noted above, however, there appears to be sufficient flexibility in Article 29 to allow inhibiting public disclosure of patent information, as evidenced by the case of secret patents in the U.S. and Japan.

⁷ See Peter Yu, *WIPO Negotiations on Intellectual Property, Genetic Resources and Associated Traditional Knowledge*, 57 *Akron L. Rev.* (forthcoming 2024) <https://ssrn.com/abstract=4656267> (“noting that “the language ‘necessary to protect the public interest’ in the second step advances the recommendation made by scholars who have long advocated for the greater consideration of the public interest in the three-step test”).

⁸ *Id.*

There are no explicit exceptions to the Convention on Biological Diversity's requirement that "[a]ccess to genetic resources shall be subject to prior informed consent" (Art. 15(5)) and that "legislative, administrative or policy measures, as appropriate," be taken "with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources." But the convention contains broad language affirming government flexibility in implementing the requirement, including in Article 15(1): "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."

Similarly, there are no exceptions to the duty in Article 17 of the Nagoya Protocol, requiring "measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources." But the state has the authority to determine what is "appropriate" and "necessary," which may be sufficient to authorize exceptions to any systems put in place.

OTHER MODELS FOR EXCEPTIONS

Using the three-step as a model for exceptions in this treaty may be ill-fitting since the IGC treaty does not require delineation of the scope of any intellectual property rights. Scholars, for example, have criticized the proposed use of the three-step test in a broadcasting instrument that is supposed to be signal-based.⁹

Many treaties requiring positive state action or regulatory action contain exceptions protecting the rights of countries to regulate in the public interest. These are often subject to a necessity or similar test.

Article XX of the General Agreement on Trade and Tariffs, incorporated into the WTO agreements, states that "nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures" that are "necessary" for a variety of public interests including "to protect public morals" and "to protect human, animal or plant life or health."

Human rights treaties often incorporate resource or temporal exceptions to state duties. So-called "positive" human rights obligations, which require,

⁹ See Hugenholtz, Bernt, *Simplifying the WIPO Broadcasting Treaty: Proposed Amendments to the Third Revised Draft* (2023). Joint PIJIP/TLS Research Paper Series. 111. <https://digitalcommons.wcl.american.edu/research/111>

for example, redistribution policies to provide social and economic benefits, are often framed as a duty to “progressively realize” the obligation over time and may be limited by availability of resources.

CONCLUDING REFLECTIONS

Drafters could follow the example of the TRIPs, the CBD, and the Nagoya Protocol, and not have any exceptions to the IGC Treaty. This would leave countries to address any perceived problems with access and benefit sharing systems retarding research or compromising other public interests to be addressed within those systems themselves. If it is accepted that some implementations merit giving governments the authority to apply exceptions to the disclosure requirement, then it may be advisable to amend the Article to remove some of the ill-fitting concepts from the 3-step test that is common in intellectual property treaties. For example, the in intellectual property law and policy discourse, “limitations” define the scope of rights conferred to intellectual property owners, such a time limited term.¹⁰ Since the treaty does not establish exclusive rights, there are no apparent reasons to introduce any “limitations,” temporal or substantive, and that concept should be eliminated from the clause.

¹⁰ World Intellectual Property Organization (WIPO). (2019). *WIPO Guide on Limitations and Exceptions in Intellectual Property*. Retrieved from <https://www.wipo.int/publications/en/details.jsp?id=4392>